DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 24 1992

Re: ZITHROMAX
Docket No. 92E-0027 #28

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. 4,517,359, filed by Pliva Pharmaceutical, Chemical, Food and Cosmetic Industry, under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ZITHROMAX, the human drug product claimed by the patent.

The total length of the review period for ZITHROMAX is 2,560 days. Of this time, 1,991 days occurred during the testing phase and 569 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 28, 1984.

   The applicant claims October 28, 1984, as the date the investigational new drug application (IND) became effective. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on October 28, 1984.

2. The date the application was initially submitted with respect to the human drug product under subsection 507 of the Federal Food, Drug, and Cosmetic Act: April 11, 1990.

   The applicant claims April 11, 1990, as the date the new drug application (NDA 50-670) was filed. FDA has verified the applicant's claim that the date NDA 50-670 became effective was on April 11, 1990.

3. The date the application was approved: November 1, 1991.

   FDA has verified the applicant's claim that NDA 50-670 was approved on November 1, 1991.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

for Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: J. Trevor Lumb
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